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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Section 3 Registration Request for Uses of Firponil in Maxforce Tick Management System Bait Station Treatment of Small Mammals (DP Barcode D281019)

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THRU: Sid Abel, Branch Chief 4/18/02
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TO: Richard Gebken, PM Team Reviewer
Registration Division (7505C)

EFED has been requested to conduct a preliminary analysis of ecological risks associated with a proposed use of fipronil for the control of ticks in wild small mammals. The purpose of the proposed public health use of the pesticide is to control deer tick infestations in foraging rodents. Small rodents such as the white-footed mouse (*Peromyscus leucopus*) are important hosts for the deer tick and reservoirs for Lyme disease.

The product proposed for use of fipronil as a control for deer tick infestation is the Maxforce Tick Management System that consists of a baiting station to attract foraging rodents and a wick application system that topically applies a solution of fipronil to the pelage of mice entering the baiting station.

Because of the containment of the fipronil product within the baiting station, EFED believes that the potential for fipronil to enter surface waters is limited. Therefore, EFED has not conducted a quantitative assessment of potential risks to aquatic organisms for this use. However, EFED believes that topical application of fipronil to the pelage of wild rodents represents a possible primary route of exposure to these organisms as well as a possible secondary route of exposure to predators of treated rodents. Based on the following assessment, EFED concludes that the risks to small mammals directly treated with the fipronil product and risks to bird and mammal predators of treated small mammals are of minimal concern. This document represents a

preliminary assessment of the risks to terrestrial wildlife from direct treatment and consumption of treated wild mammals.

Risk of direct topical application of fipronil to wild mammals

Fipronil application to small mammals is achieved in the Maxforce product when an individual animal comes in contact with a wick material. According to available statements of formulation, the wick material contains approximately 25.5 mg fipronil. A most conservative assessment of exposure would be to assume that 100 percent of the available material is released to a single organism. Using a typical white-footed mouse body weight of 25 g, a release of the entire content of fipronil to such an individual would result in a total external dose of approximately 1000 mg/kg. Assuming 100 percent absorption of the material would result in an internal dose of 1000 mg/kg. Comparison of this conservative exposure estimate with the available acute oral toxicity data for fipronil (rat LD_{50} 97 mg/kg, MRID 42918628) would yield a risk quotient (dose/toxicity threshold = RQ) of 10. Assumption of only 5 percent absorption of topical fipronil would still yield an RQ at the level of acute concern (RQ 0.5). However, EFED does not believe that the assumption of total release of wick material to a single organism is a reasonable scenario.

In order to estimate a more realistic application dose to mice, EFED turned to available mammal residue data collected from field trials of the product (MRID 45572304). White-footed mice were collected from bait station trials with the Maxforce product and solvent extracted for fipronil residues. The maximum measured residue from a field sampled mouse was 321 ng. Assuming a minimal mouse mass of 14 g, this corresponds to a maximum measured external dose of 97 ug/kg. Even assuming a 100 percent absorption rate, the estimated internal dose to such an exposed individual would yield an acute RQ of 0.001 when compared with the rat LD_{50}. This is well below EFED acute effects, restricted use, and endangered species levels of concern.

EFED also compared the field data estimate of maximum external dose (97 ug/kg) with the rat reproduction no adverse effect level (NOAEL) of 2.54 mg/kg-bw (MRID 42918647). Again, assuming a conservative 100 percent dermal absorption, the resulting internal dose of 97 ug/kg is well below the threshold for reproduction effects and results in an RQ well below the EFED level of concern for chronic effects.

Based on the above assessment, EFED believes that the acute and chronic risks of fipronil direct treatment to small mammals from the Maxforce product are below levels of concern.

Risk of indirect exposure through predation on fipronil-treated wild mammals

EFED used the MRID 45572304 maximum measured mass of fipronil on treated white-footed mice (321 ng) to assess the potential acute and chronic risks to wild mammals and birds that may consume treated mice. As in the case of assessing dose to treated mice, assuming a maximum measured fipronil mass applied to a small 14 g white-footed mouse yields a theoretical concentration of 97 ug/kg mouse. This value can be directly compared with acute and reproduction endpoints for birds to assess the potential risk to raptors and other birds that may

prey on small mammals. The lowest available acute LC_{50} for birds is 48 mg/kg-diet (MRID 42918620) and the lowest reproduction threshold for birds is 10 mg/kg-diet (MRID 42918622). The estimated concentration of fipronil in treated mice is well below both the acute and reproduction endpoints, with acute and reproduction RQs of 0.002 and 0.0097, respectively.

Mammalian predator risks were evaluated for reproduction effects in a manner similar to the bird assessment. The estimated mouse concentration of 97 ug/kg was compared to the rat reproduction NOAEC of 30 mg/kg-diet (MRID 42818647). The resulting RQ (mouse concentration/ NOAEC) of 0.0003 is well below EFED's level of concern (RQ = 1.0). Because the acute toxicity endpoint is expressed as a dose level and not dietary concentration, EFED converted the estimated treated mouse fipronil concentration to a predator dose by conservatively assuming that the predator eats 100% of it's body weight in mice each day. This converts the 97 ug/kg-diet concentration of mouse prey to a predator daily oral dose of 97 ug/kg-bw. This conservatively estimated dose, when compared to the lowest mammal LD_{50} of 97 mg/kg-bw (rat), yields an acute RQ of 0.001, again well below EFED levels of concern.

On the basis of the above analysis, EFED concludes that the acute and reproduction risks of Maxforce fipronil product use to bird and mammal predators of treated mice is below concern.